

# Aerex™ FC Cartridge Filters

0.2 µm Rated

Catalogue Number: CTGB71TP3

Lot Number: C6SN98709

## Good Manufacturing Practices

This product was manufactured in a Millipore facility which meets or exceeds FDA Device Good Manufacturing Practice standards.

## ISO 9000 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

## Non-Fiber Releasing

This product was manufactured with a PTFE membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6)

## Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

## 100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test.

## Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications.

### USP Bacterial Endotoxins

A cartridge aqueous extraction contains less than 0.5 EU/ml as determined using the Limulus Amebocyte lysate (LAL) test.

### Integrity

Samples exhibited a bubble point equal to or greater than 13 psig (900 mbar), in a 60/40% IPA/water mixture using nitrogen as the test gas at 23 °C.

Samples exhibited a nitrogen diffusional flow rate of less than or equal to 1.5 cc/min at 10 psig (690 mbar) in a 60/40% IPA/water mixture at 23 °C per 10-inch cartridge.

Samples exhibited a HydroCorr test value less than or equal to 0.40 mL/min per 10-inch cartridge at 20 psig (1380 mbar).

### Thermal and Hydraulic Stress

Samples were steamed in place at 145 °C and maintained integrity after a forward stress to 100 psid (6.9 bar) and a reverse stress to 75 psid (5.2 bar).

### Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 1.2 psid (83 mbar) at an air flow rate of 100 SCFM (170 nm<sup>3</sup>/hr) and 30 psig (2.1 bar) inlet air pressure at 23 °C per 10-inch cartridge.

## Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

### Toxicity

This product is non-toxic per the current USP General (Mouse) Safety Test.

### Gravimetric Extractables

The extractables level was equal to or less than 35 mg per 10-inch cartridge after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

### Multiple Sterilization Cycles

Integrity was maintained after 150 forward and 50 reverse steam-in-place cycles of 30 minutes at 145 °C.

### Integrity After Steaming

Integrity was maintained on cartridges steamed 165 hours at 145 °C.

### Virus Aerosol Retention

This product has been qualified to retain a φX174 virus aerosol challenge of 10<sup>9</sup> to 10<sup>10</sup> PFU at an air flow rate of 50 SCFM per 10-inch cartridge after 50 steam-in-place cycles at 145 °C.

### Bacterial Grow-Through

The membrane has been qualified to retain bacteria when challenged for 21 days with a minimum *Brevundimonas dimorpha* aerosol concentration of 1 x 10<sup>7</sup> CFU/cm<sup>2</sup>.



Peter Eichert  
BioPharmaceutical Quality Manager

MILLIPORE